1649

Docket No.: 13173-00008-US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ute Heim et al.

Conf. No.: Not yet assigned

Application No.: 10/527,375

Group Art Unit: Not yet assigned

Filed: March 10, 2005

Examiner: Not Yet Assigned

For: TRANSGENIC EXPRESSION CASSETTES FOR THE EXPRESSION OF NUCLEIC ACIDS IN CARBOHYDRATE-STORING SINK TISSUES OF PLANTS

TRANSMITTAL OF TRANSLATION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants enclose herewith the Translation of the International Preliminary Examination Report.

Applicants believe no fee is due with this communication. However, if a fee is due, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 13173-00008-US, from which the undersigned is authorized to draw.

Respectfully submitted,

By Robert Makowski

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PTO/SB/92 (09-04)
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Application No.: 10/527,375 Attorney Docket No.: 13173-00008-US

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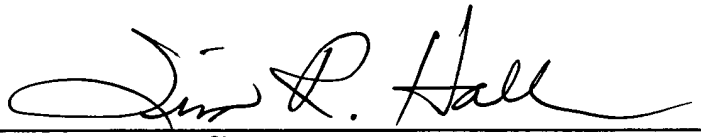

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PCT/EP2003/00985

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PATENT COOPERATION TREATY

Patente, Marken u. Lizenzen
20. April 2005

From the INTERNATIONAL BUREAU

PCT

To:
AS

NOTIFICATION OF TRANSMITTAL OF COPIES OF TRANSLATION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 72.2)

BIEBERBACH, Andreas
c/o BASF Aktiengesellschaft
67056 Ludwigshafen
ALLEMAGNE

EL Phase Seendet 01.03.05

Date of mailing *(day/month/year)* 14 April 2005 (14.04.2005)	
Applicant's or agent's file reference 0000053913	**IMPORTANT NOTIFICATION**
International application No. PCT/EP2003/009855	International filing date *(day/month/year)* 05 September 2003 (05.09.2003)
Applicant SUNGENE GMBH & CO. KGAA et al	

1. **Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. **Transmittal of the copy of the translation to the elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

AZ, CA, CH, CN, CO, GH, KG, KP, KR, MK, MZ, RU, TM

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

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3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Agnes Wittmann-Regis
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 89 70

Form PCT/IB/338 (July 1996)

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Translation

PCT/EP2003/009855

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000053913	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/009855	International filing date (*day/month/year*) 05 September 2003 (05.09.2003)	Priority date (*day/month/year*) 10 September 2002 (10.09.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/82, A01H 5/00		
Applicant SUNGENE GMBH & CO. KGAA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 03 April 2004 (03.04.2004)	Date of completion of this report 26 August 2004 (26.08.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/009855

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-55, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages 1-18, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:

pages 1/5-5/5, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in written form.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims		YES
	Claims	1-18	NO
Inventive step (IS)	Claims		YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations

1. This report refers to the following document, D1, cited in the search report; the same numbering will be used throughout the procedure:

D1: BUCHNER P ET AL: "GLUCAN PHOSPHORYLASES IN VICIA FABA L.: CLONING, STRUCTURAL ANALYSIS AND EXPRESSION PATTERNS OF CYTOSOLIC AND PLASTIDIC FORMS IN RELATION TO STARCH" PLANTA, SPRINGER VERLAG, DE, Vol. 199, 1996, pages 64-73, XP002071466 ISSN: 0032-0935

2. Clarity (PCT Article 6), novelty and inventive step (PCT Article 33(2) and (3))

2.1 The objections relating to a lack of clarity indicated in this report make it difficult to provide a conclusive opinion with respect to the novelty and inventive step in claims 1 to 18.

2.2 The present claims are worded so unclearly that there is considerable doubt as to the range of protection, and delimitation of the range of protection in relation to the prior art is made considerably difficult.

The use of expressions such as "transgenic expression" (claim 1) "transgenic expression cassette" and "transgenic expression vector" (claim 11) result in a lack of clarity, since the meaning thereof is not clear from the wording of the claim alone. For clarification it is pointed out that expression cassettes and expression vectors may be used for producing transgenic organisms, but describing them as being "transgenic" themselves means nothing in a technical sense.

Furthermore, it is not clear whether the description "plastidic 1,4-alpha-D-glucan-phosphate-alpha-D-glucosyl transferase" in claim 1 concerns a sequence derived from the nuclear genome (and subsequently transferred into the plastids) or from the plastome.

Phrases such as "essentially not expressed in source tissues" in claim 1 are not recommended, since they involve relative expressions that have no generally recognised meaning. The same objection applies to the wording "substantially the same promoter activity" in claims 2 and 8.

2.3 The wording of claim 1 c) is so unclear that it raises doubt concerning the structure and architecture of the expression vector and thus concerning the scope for which protection is sought.

In addition, phrases such as "functionally equivalent promoter sequences", "functionally equivalent fragments", "functional equivalent" and "functionally equivalent fragments" do not help to make claims 2, 3, 8 and 9 clear.

2.4 Claim 2 ii) concerns promoter sequences which have "at least 40% homology with the sequence as per SEQ ID NO:1 over a sequence section of at least 100 base pairs".

A search of known databases has shown that nucleic acid sequences that have 40% "homology" with SEQ ID NO:1 and can therefore be regarded as "functionally equivalent promoter sequences" are already known in the prior art. It is not assumed that sequences of completely different origin which have such a low "homology" would also have corresponding promoter activity, like the sequence defined by SEQ ID NO:1.

The nucleotide sequence characterised by SEQ ID NO:1 has homologies with already known nucleic acid sequences from different organisms (see, for example: EMBL Accession No. AC024835, *Caenorhabditis elegans cosmid* Y57E12B, this genomic DNA fragment has 60% identity with SEQ ID NO:1 in 447 base pairs; EMBL Accession No. AC131094, *Homo sapiens* BAC clone RP11-598D14, this genomic DNA fragment has 57% identity with SEQ ID NO:1 in 663 base pairs; EMBL Accession No. AL069526, *Drosophila melanogaster* BAC clone BACR29M12 of RPCI-98 library, this genomic DNA fragment has 52% identity with SEQ ID NO:1 in 403 base pairs).

The above are thus "functionally equivalent promoter sequences" with "substantially the same promoter activity" as the promoter sequence described by SEQ ID NO:1; see claim 3.

2.5 The subject matter of claim 3 appears to concern promoter sequences. Claim 6 concerns "isolated nucleotide sequences" as per claim 3, with particular reference to SEQ ID NO:3. A database search, however, showed that the sequence characterised by SEQ ID NO:3 has 99% identity with the alpha-1,4-glucan phosphorylase-specific precursor mRNA from document D1. Consequently, with strict interpretation of the wording of the present claims, the sequence disclosed in document D1 would be regarded as a "functionally equivalent fragment" of the promoter sequence described by SEQ ID NO:1.

2.6 The wording of the claims should be modified such that the meaning is clear from the wording of the claims alone and makes sense technically.

2.7 In view of the specified objections relating to a lack of clarity, the related uncertainty regarding the scope of protection of the claims concerned and the delimitation thereof in relation to the prior art, it does not appear possible to the examiner to currently provide a conclusive, positive opinion regarding the novelty and inventive step in claims 1 to 18.

3. Support in the description (PCT Article 6)

3.1 The "transgenic organism" in claim 13 covers all conceivable single-cell and multi-cell organisms that are transformable. The promoter disclosed in the description, however, is a plant-specific promoter, the activity of which is particular to plant-specific development stages, tissues, cells and organ cells. In view of the lack of support and

of general understanding, it is not assumed that the stated sequence, characterised by SEQ ID NO:1, would have a similar promoter activity or would be at all active in other non-plant host organisms.

Claims 13 to 15 should therefore concern only the plant organisms disclosed in the application.